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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,108	05/14/2002	Paulus Hubertus Andreas Quax	101137-34	7820

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/019,108	<b>Applicant(s)</b> QUAX ET AL.	
	<b>Examiner</b> Anne Marie S. Wehbe	<b>Art Unit</b> 1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Claims 1-12 are pending and under examination in the instant application. An action on the merits follows.

#### ***Specification***

The preliminary amendment filed on 12/20/01 added an abstract of the disclosure. However, the abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

#### ***Priority***

A certified copy of applicant's priority document, EPO 99202051.1, was received on 12/20/01. The office acknowledges benefit of priority to the filing date of the foreign priority document. The effective filing date of the instant application is 6/24/99.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 3, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 4-5, the phrases "preferably", "most preferably", or "most particularly" render the claims indefinite because it is unclear whether the limitations following the phrase are intended as examples or whether they are meant to further limit the claimed invention. Claim 6 depends on claim 5 and thus is subject to this rejection.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, and 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Soma et al. (1995) Circ. Res., Vol. 76 (3), 405-411. The applicant claims a non-human test mammal

susceptible to the induction of atherosclerosis which carries a vessel-restricting device applied to at least one of its blood vessels. The applicant further claims said test mammal wherein the device is a cuff or ring made of plastic, or wherein the test animal is a rabbit. In addition, the applicant claims methods of accelerating the onset of atherosclerosis in a non-human test mammal by placing the vessel restricting device on a least one blood vessel, and methods of using said test mammal to screen or test for substance, diets, or treatments which have anti-atherosclerotic effects by administering the substance, diet, or treatment to the animal and comparing the effect in the test animal to a control animal. The applicant also claims said methods wherein the test animal and control animal are fed an atherosclerosis-promoting diet.

Soma et al. teaches a model for neointimal thickening associated with atherosclerosis comprising a rabbit in which extra-arterial Silastic collars were placed around both carotid arteries (Soma et al., page 405, and 406). Soma et al. further teaches the treatment of the rabbits with a cholesterol rich diet for 21 days prior to the placement of the collars and the comparison of the effects of the diet on intimal thickness on rabbits having collars versus rabbits fed the diet without the collars, demonstrating that the presence of the collar induces neointimal thickening (Soma et al., page 406, and page 407, Figure 2). Soma et al. further teaches testing the effects of rA-Im/A-Im on intimal thickening in the rabbit model, and observing that rA-Im/A-Im treatment inhibits neointimal hyperplasia in the cholesterol-fed rabbits containing the collars compared to the control groups (Soma et al., page 408). Thus, by teaching all the limitations of the claims as written, Soma et al. anticipates the instant invention as claimed.

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Claims 1-5 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Moroi et al. (March, 1998) J. Clin. Invest., Vol. 101 (6), 1225-1232. The applicant claims a non-human test mammal susceptible to the induction of atherosclerosis which carries a vessel-restricting device applied to at least one of its blood vessels. The applicant further claims said test mammal wherein the device is a cuff or ring made of plastic, or wherein the test animal is a transgenic mouse with a disorder promoting its susceptibility to atherosclerosis. In addition, the applicant claims methods of accelerating the onset of atherosclerosis in a non-human test mammal by placing a vessel restricting device on a least one blood vessel.

Moroi et al. teaches transgenic eNOS mutant mice which demonstrate enhanced intimal growth in response to injury, and a mouse model of atherosclerosis comprising an eNOS mutant mouse which has a polyethylene cuff placed around the femoral artery (Moroi et al., page 1225). Moroi et al. further teaches the enhancement of intimal thickness in cuffed mice compared to controls in a 14 day period (Moroi et al., page 1226). Thus, by teaching all the elements of the claims as written, Moroi et al. anticipates the instant invention as claimed.

Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,310,270 B1 (10/30/01), hereafter referred to as Huang et al. The applicant claims a non-human test mammal susceptible to the induction of atherosclerosis which carries a vessel-restricting device applied to at least one of its blood vessels. The applicant further claims said test mammal wherein the device is a cuff or ring made of plastic, or wherein the test animal is a transgenic mouse, particularly an APOE<sup>-/-</sup>, LDL-R<sup>-/-</sup> or ApoE3 mouse. In addition, the applicant claims methods of accelerating the onset of atherosclerosis in a non-human test mammal by placing the

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vessel restricting device on a least one blood vessel, and methods of using said test mammal to screen or test for substance, diets, or treatments which have anti-atherosclerotic effects by administering the substance, diet, or treatment to the animal and comparing the effect in the test animal to a control animal. The applicant also claims said methods wherein the test animal and control animal are fed an atherosclerosis-promoting diet.

Huang et al. teaches transgenic animals useful for screening for compounds that have therapeutic effects on atherosclerosis, wherein the transgenic animals are  $eNOS^{-/-}$  or double mutant  $eNOS^{-/-}/APOE^{-/-}$  or  $eNOS^{-/-}/LDL-R^{-/-}$  mice which have increased propensity to develop atherosclerosis (Huang et al., abstract, column 4, column 16, columns 38-39, and claim 14). Huang et al. further teaches feeding the knock-out mice with a high cholesterol diet and further teaches placing a polyethylene cuff around the femoral artery to induce atherosclerosis (Huang et al., column 33-34, and columns 38-39). Huang et al. further teaches using the knock-out mice having a cuff around the femoral artery to test compounds for use in treating atherosclerosis (Huang et al., claim 25). Thus, by teaching all the limitations of the claims as written, Huang et al. anticipates the instant invention as claimed.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the

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technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbé', written in a cursive style.